STATE OF VERMONT
GREEN MOUNTAIN CARE BOARD

In re: Application of Mary Hitchcock Memorial Hospital/Norris Cotton Cancer Center-North, Replacement of Linear Accelerator	)))))	GMCB-005-15con

STATEMENT OF DECISION AND ORDER

Introduction

Applicant Mary Hitchcock Memorial Hospital (MHMH), doing business as Norris Cotton Cancer Center-North (NCCC) seeks a Certificate of Need (CON) to purchase and install a new Varian TrueBeam linear accelerator at NCCC in a newly constructed vault, and to maintain the existing Varian 2100 EX linear accelerator. The total cost of the project is $4,807,365.

For the reasons outlined below, we approve the application.

Procedural Background

On February 2, 2016, MHMH filed a CON application with the Green Mountain Care Board. After public notice, the Board granted expedited review of the application pursuant to 18 V.S.A. § 9440(c)(5). The Board requested additional information from the applicant on April 1, 2016, which the applicant provided on May 3, 2016. Because it inadvertently omitted projected treatment information, the applicant revised and resubmitted its responses to the Board's request on May 26, 2016. The application was closed on June 15, 2016. The Board received no requests for intervention in this matter and received no public comments.

Findings of Fact

1. MHMH is a tertiary hospital in Lebanon, New Hampshire with a service area population of approximately 1.9 million people located primarily in Vermont and New Hampshire. MHMH is affiliated with the Dartmouth-Hitchcock Clinic, a multi-specialty physician group practice with over 1,000 primary and specialty care physicians, and has resource- and service-sharing affiliations with a number of smaller hospitals located throughout Vermont and New Hampshire. Application (App.) at 11.

2. MHMH is the operator of NCCC in St. Johnsbury, one of 45 Comprehensive Cancer Centers designated by the National Cancer Institute. App. at 11. NCCC offers a full range of radiation therapy, chemotherapy, and specialized cancer services such as familial cancer/cancer risk assessments and palliative care. *Id*. at 24.

3. NCCC is proposing to purchase a new Varian TrueBeam linear accelerator for use in radiation therapy and to construct a vault in which it will be housed. In addition, it is

proposing to maintain its current accelerator, a Varian 2100 EX, in its existing vault for use as a backup unit during maintenance of the new unit or during peak periods of patient volume. NCCC intends to limit the simultaneous use of the units to periods in which patient volume exceeds the new unit's capacity. App. at 12.

4. NCCC began operating its existing linear accelerator in 2005 to serve a population of approximately 70,000 residing in a largely rural area that includes Caledonia and Essex counties in Vermont, and Coos County and parts of Grafton County in New Hampshire. App. at 32. NCCC expected that the St. Johnsbury location would reduce service volume at the linear accelerator facility in Lebanon, New Hampshire; instead, the St. Johnsbury facility exceeded its projected first year volume targets with only limited reduction of volume at the Lebanon site. *Id*. at 22.

5. Patients receiving radiation therapy typically require 15 minutes of treatment per day, five days per week, for five to six weeks. App. at 33. Prior to 2005, cancer patients in northeastern Vermont needing radiation therapy had to travel significant distances for their treatment. Currently, the closest linear accelerators to patients in the region are located in Berlin, Vermont and Lebanon, New Hampshire. *Id*. at 22, 25.

6. NCCC delivered 5,940 radiation treatments from April 2015 through March 2016. Responses to Questions (Responses) (May 26, 2016) at 3. The applicant projects that it will deliver 6,118 treatments from April 2016 through March 2017, 6,302 treatments from April 2017 through March 2018, and 6,491 treatments from April 2018 through March 2019. *Id.* The applicant plans to begin use of the new accelerator in April 2017. App. at 23.

7. The existing Varian 2100 EX is ten years old, fully depreciated, and is built on a platform originally deployed thirty years ago. For the period from June 29, 2015 through November 11, 2015, the applicant experienced nine days of unit downtime, resulting in 107 missed patient treatments. The applicant considers this to be an unacceptable level of reliability. App. at 19.

8. Compared to the Varian 2100 EX, the Varian TrueBeam has advanced capabilities that include higher energy X-rays able to treat tumors at greater bodily depth, and more advanced imaging and monitoring functions. In addition, the Varian TrueBeam can be used for volumetric-modulated arc therapy, intensity-modulated radiation therapy, and for conventional 3D conformal therapy. No new services will be added as a result of this project. App. at 16-17.

9. The applicant considered placing the new accelerator in the existing vault, which would create savings of approximately $190,000. NCCC rejected this option because it would need to renovate the existing vault to fit the new, larger accelerator, which would halt all radiation treatments at the facility during the period of construction. The resulting unavailability of services at the facility would impose financial and travel burdens for patients requiring treatment and on their families, and could result in deferred patient care. App. at 21, 29.

10. Despite the increased capabilities of the proposed new accelerator, the existing equipment can safely treat most conditions. At times when only the existing accelerator is available, the choice of delaying treatment versus receiving treatment on the existing accelerator will be a shared decision between the physician and the patient. Responses (May 26, 2016) at 5.

11. To ensure appropriateness of care consistent with evidence-based guidelines, all patient treatment plans undergo peer review at weekly MHMH Radiation Oncology chart rounds held by videoconference. Monthly Quality Assurance and Quality Improvement meetings are held to ensure standards of patient safety, access and evidence-based guidelines are delivered to patients. As a National Cancer Institute designated comprehensive cancer center and one of the 47 full members of the Radiation Therapy Group, MHMH and NCCC have oversight by the Imaging and Radiation Oncology Core physics group in Houston, Texas, which provides routine quality assurance checks on equipment and calibration protocols. MHMH is fully accredited by the American Board of Radiology, and NCCC's radiation oncologists must maintain certification from the American Board of Radiology. App. at 27-29.

12. Construction of the new vault meets applicable FGI guidelines for the Design and Construction of Health Care Facilities. All new equipment and systems are designed to be energy efficient. App. at 30-32.

13. The total project cost is $4,807,365, which MHMH plans to fund with working capital, thereby incurring no new debt. App. Tables 1, 2. MHMH projects that the average annual increase in cost of services will not exceed 3.0%. App. at 39.

Standard of Review

Vermont's CON process is governed by 18 V.S.A. §§ 9431-9446 and Green Mountain Care Board Rule 4.000 (Certificate of Need). The applicant bears the burden to demonstrate that each of the criterion set forth in 18 V.S.A. § 9437 is met. Rule 4.000, § 4.302(3). We review each of these criterion below.

Conclusions of Law

Pursuant to 18 V.S.A. § 9437(1), we conclude that the application is consistent with Vermont's Health Resource Allocation Plan (HRAP). The HRAP, last published in 2009, identifies needs in Vermont's health care system, resources to address those needs, and priorities for addressing them on a statewide basis. The HRAP contains two specific requirements for the purchase of linear accelerators. First, under Standard 3.25, an applicant must demonstrate that the proposed accelerator will be used for at least 6,000 treatments per year by the second year of operation. Here, NCCC performed 5,940 treatments during the most recent period (April 2015 through March 2016), which included unit downtime that resulted in 107 missed treatments. Findings of Fact (Findings) ¶¶ 6, 7. Projecting this experience period forward, the applicant anticipates delivering 6,302 treatments in the year beginning April 2017, and 6,491 the following year, with the new unit functional as of April 2017. Finding ¶ 6. We find these projections are reasonable and satisfy Standard 3.25.

The applicant must also meet Standard 3.26, which requires that any radiation therapy service outside a tertiary center have formal links with a tertiary center that performs ongoing utilization review and quality assessment. MHMH is a tertiary hospital and the operator of NCCC, which does not have its own corporate identity, meeting this requirement. Finding ¶1. Even if they were separate entities, NCCC's procedures for utilization review and quality monitoring would satisfy this standard.

We conclude that the application is consistent with the more general requirements of the HRAP and has therefore satisfied the first criterion.

Pursuant to the second statutory criterion, 18 V.S.A. § 9437(2), we conclude that MHMH has shown that the cost of the project is reasonable. The applicant will be funding the proposed purchase and vault construction entirely by cash allocated through its annual operating budget, and will not burden future operations through any short- or long-term debt financing. Finding ¶13. The project will not unduly increase the cost of medical care in Vermont because the facility is geographically distant from others offering similar treatment, and its services have proven to benefit a rural and relatively isolated population without significantly affecting utilization at other facilities. Finding ¶ 4. Finally, there is no less expensive alternative to the proposed purchase. Although the applicant considered using the existing vault to house the new unit, estimated to save $190,000 in overall costs, the unavailability of services during renovation would impose hardships on patients requiring treatments and on their families, and could result in deferred care and diminished health outcomes. In addition, it would eliminate the added capacity as a result of maintaining the existing unit as a backup while the new unit receives maintenance or in periods of peak volumes. Findings ¶ 3, 9.

Pursuant to the third criterion, 18 V.S.A. § 9437(3), MHMH has demonstrated both an existing and reasonably anticipated need for the proposed project. NCCC has provided radiation oncology services since 2005. Prior to 2005, residents of northeastern Vermont needing radiation treatment for cancer had to travel significant distances to receive their treatments. Finding ¶ 4. Failing to replace the existing accelerator with a more reliable unit would limit patients' access to treatment, and create unnecessary travel, financial and emotional burdens for cancer patients and their families. We conclude that the applicant has demonstrated both a current and future need for these services.

The applicant has also satisfied the fourth criterion, 18 V.S.A. § 9437(4), by demonstrating that the project will increase the quality of and access to health care for Vermonters. Quality will improve because the new accelerator has advanced capabilities, with better imaging than the existing unit and the ability to target tumors at greater depths in the body. Finding ¶ 8. In addition, because there will be less unit downtime once NCCC acquires a more advanced and reliable linear accelerator, both quality of care and access to care will improve. *See* Finding ¶ 3 (applicant will retain existing unit for backup during periods of peak volume or maintenance.

We further conclude that MHMH's proposed purchase is consistent with the remaining statutory criteria to the limited extent they are applicable. The project will not have an undue adverse impact on other existing services provided by the applicant because the proposed project maintains a core service it already provides; the ways in which the project will serve the public

good have been adequately addressed in our discussion of other criteria; the project will mitigate rather than increase transportation difficulties for the served population; and the project is not an information technology purchase as contemplated in 18 V.S.A. § 9351. *See* 18 V.S.A. § 9737(5), (6), (7), (8).

Accordingly, we conclude that the applicant has met the necessary statutory criteria, and issue a certificate of need on this date.

Order

Pursuant to 18 V.S.A. § 9440(d), the Green Mountain Care Board approves the application of Mary Hitchcock Memorial Hospital, doing business as Norris Cotton Cancer Center-North, and a Certificate of Need shall issue.

SO ORDERED.

Dated: July 26, 2016 at Montpelier, Vermont

s/ Alfred Gobeille)
)
s/ Cornelius Hogan) GREEN MOUNTAIN
) CARE BOARD
s/ Jessica Holmes) OF VERMONT
)
s/ Betty Rambur)
)
s/ Allan Ramsay)

Filed: July 26, 2016

Attest: s/ Janet Richard
Green Mountain Care Board
Administrative Services Coordinator